

BS 6256:2021



BSI Standards Publication

**Packaging for terminally-sterilized
medical devices — Method for
determination of methylene blue
particulate penetration**

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Summary of pages

This document comprises a front cover, and inside front cover, pages i to iv, pages 1 to 27, an inside back cover and a back cover.

Foreword

Publishing information

This British Standard is published by BSI Standards Limited, under licence from The British Standards Institution, and came into effect on 31 January 2021. It was prepared by Technical Committee CH/198, *Sterilization and Associated Equipment and Processes*. A list of organizations represented on this committee can be obtained on request to its committee manager.

Supersession

This British Standard supersedes [BS 6256:1989](#), incorporating amendment 1, which is withdrawn.

Information about this document

[BS 6256:1989](#) specified requirements for materials, performance, marking and packaging for paper used in the manufacture of steam sterilization paper bags, pouches and reels. These requirements have been superseded by the adoption as British Standards of European Standards in the EN ISO 11607 series and EN 868 series (see Bibliography).

Annex C to [BS 6256:1989](#) provided a test method for determination of methylene blue particulate penetration of packaging material. This test method is referenced in BS EN ISO 11607-1 but has not been incorporated into that standard nor into the BS EN 868 series. This British Standard contains only the test method from the 1989 edition of BS 6256 and retains the same BS identifier in order to maintain the integrity of the reference from BS EN 11607-1.

Annex C to [BS 6256:1989](#) normatively referenced [BS 2577:1955](#) and [BS 3431:1961](#), which have been withdrawn. The necessary content of these standards has therefore been incorporated into this new edition.

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its methods are expressed as a set of instructions, a description, or in sentences in which the principal auxiliary verb is “shall”.

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

The word “should” is used to express recommendations of this standard. The word “may” is used in the text to express permissibility, e.g. as an alternative to the primary recommendation of the clause. The word “can” is used to express possibility, e.g. a consequence of an action or an event.

Notes and commentaries are provided throughout the text of this standard. Notes give references and additional information that are important but do not form part of the recommendations. Commentaries give background information.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. “organization” rather than “organisation”).

Where websites and webpages have been cited, they are provided for ease of reference and are correct at the time of publication. The location of a webpage or website, or its contents, cannot be guaranteed.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

0 Introduction

The process of designing and developing a packaging system for terminally sterilized medical devices is a complicated and critical endeavour. The device components and the packaging system need to be combined to create a product that performs efficiently, safely, and effectively in the hands of the user. The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation. The specific nature of the medical device, intended sterilization method(s), intended use, expiry date, transport and storage all influence the packaging system design and choice of materials. The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device.

BS EN ISO 11607-1 specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices, while considering the wide range of potential materials, medical devices, packaging system designs and sterilization methods.

BS EN ISO 11607-2 describes the validation requirements for forming, sealing and assembly processes.

[BS EN 868](#) Parts 2 to 10 specify particular requirements for a range of commonly used materials. Compliance with [BS EN 868](#) Parts 2 to 10 can be used to demonstrate compliance with one or more of the requirements of BS EN ISO 11607-1.

BS EN 11607-1 requires that porous materials provide an adequate microbial barrier to microorganisms in order to provide integrity of the sterile barrier system and product safety. It continues by noting that there is no universally accepted method of demonstrating microbial barrier properties. Evaluation of the microbial barrier properties of porous materials is typically conducted by challenging samples with an aerosol of bacterial spores or particulates under a set of test conditions which specify the flow rate through the material, challenge to the sample and duration of the test. The microbial barrier properties of the material, under these specified test conditions, are determined by comparing the extent of bacterial or particulate penetration through the material with that of the original challenge. Data from a validated physical test method that correlates with a validated microbiological challenge method are considered acceptable for determining the microbial barrier properties. As validated microbial challenge methods for materials and sterile barrier systems become available, they will be considered for inclusion in future editions of BS EN ISO 11607-1.

BS EN ISO 11607-1:2009+A1:2014, Annex B lists standardized test methods and procedures that may be used to demonstrate compliance with the requirements of BS EN ISO 11607-1. The method described in this British Standard is listed as one of the possible methods of demonstrating microbial barrier properties. This method is based on a test method described in [BS 2577](#) (withdrawn) that was developed to assess the protection afforded by respirator cannisters containing a filtering medium against particulate clouds.

1 Scope

This British Standard describes methods of demonstrating the performance of the microbial barrier of porous material used in a sterile barrier system by penetration of particles of methylene blue.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions of this document¹⁾. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN 20187, *Paper, board and pulps – Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples*

3 Terms and definitions

No terms and definitions are listed in this document.

NOTE ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- a) ISO Online browsing platform: available at <https://www.iso.org/obp>; and
- b) IEC Electropedia: available at <http://www.electropedia.org/>.

4 Principle

COMMENTARY ON CLAUSE 4

The layout of the apparatus is illustrated in [Figure 1](#) and [Figure 2](#).

The atomizer, working under a constant pressure and flow of compressed air, disperses a solution of methylene blue into a mist at a uniform rate. The mist passes into the evaporation tube (E) where it is diluted to a total volume of 30 dm³/min by dry air entering at (B). The droplets of solution evaporate before reaching the control cock (C), leaving a residue of solid particles of methylene blue. When the control cock (C) is in the test position, the test cloud passes to the test circuit which contains the sample under test and the filter paper.

When the control cock is turned to the central or air position, the cloud is diverted to the by-pass circuit and at the same time air is drawn through the test circuit. In the off position of the control cock, the cloud remains diverted to the by-pass circuit, but there is no flow through the test circuit. The rates of flow in the circuits are adjusted to 30 dm³/min by means of the air valves V₂ and V₃.

To test a sample, the control cock is first turned to the off position and the sample and filter paper are inserted into their respective holders. The test cloud is then passed to the sample for a predetermined time, following which air is passed for a further period of 2 s in order to sweep out the residual cloud from the test circuit. The control cock is then turned to off and the filter paper removed. Finally, the test stain is developed with steam and the penetration assessed by comparing the stain with the standard stains.

¹⁾ Documents that are referred to solely in an informative manner are listed in the Bibliography.

Figure 1 — Circuit diagram of apparatus for methylene blue particulate penetration test

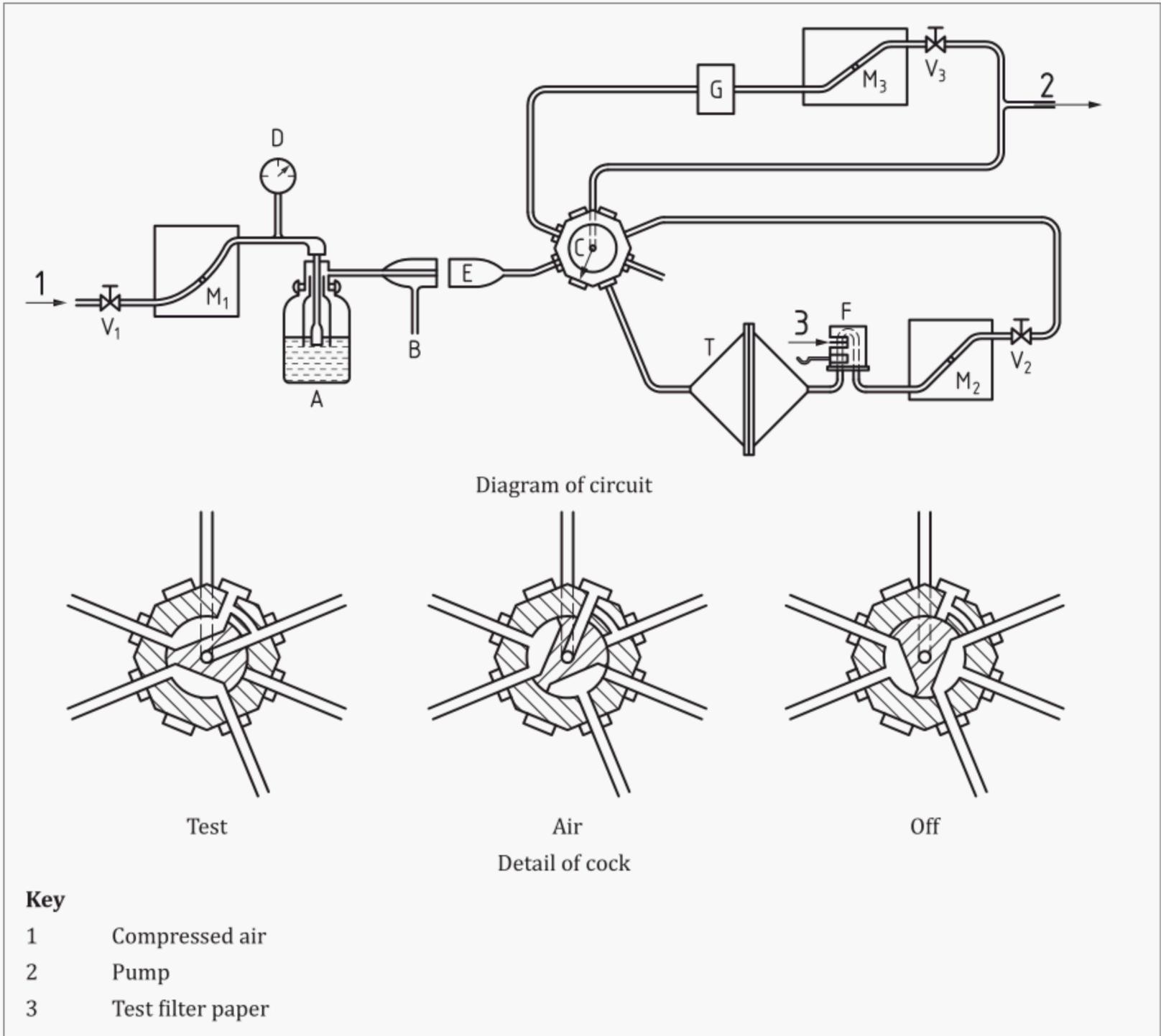
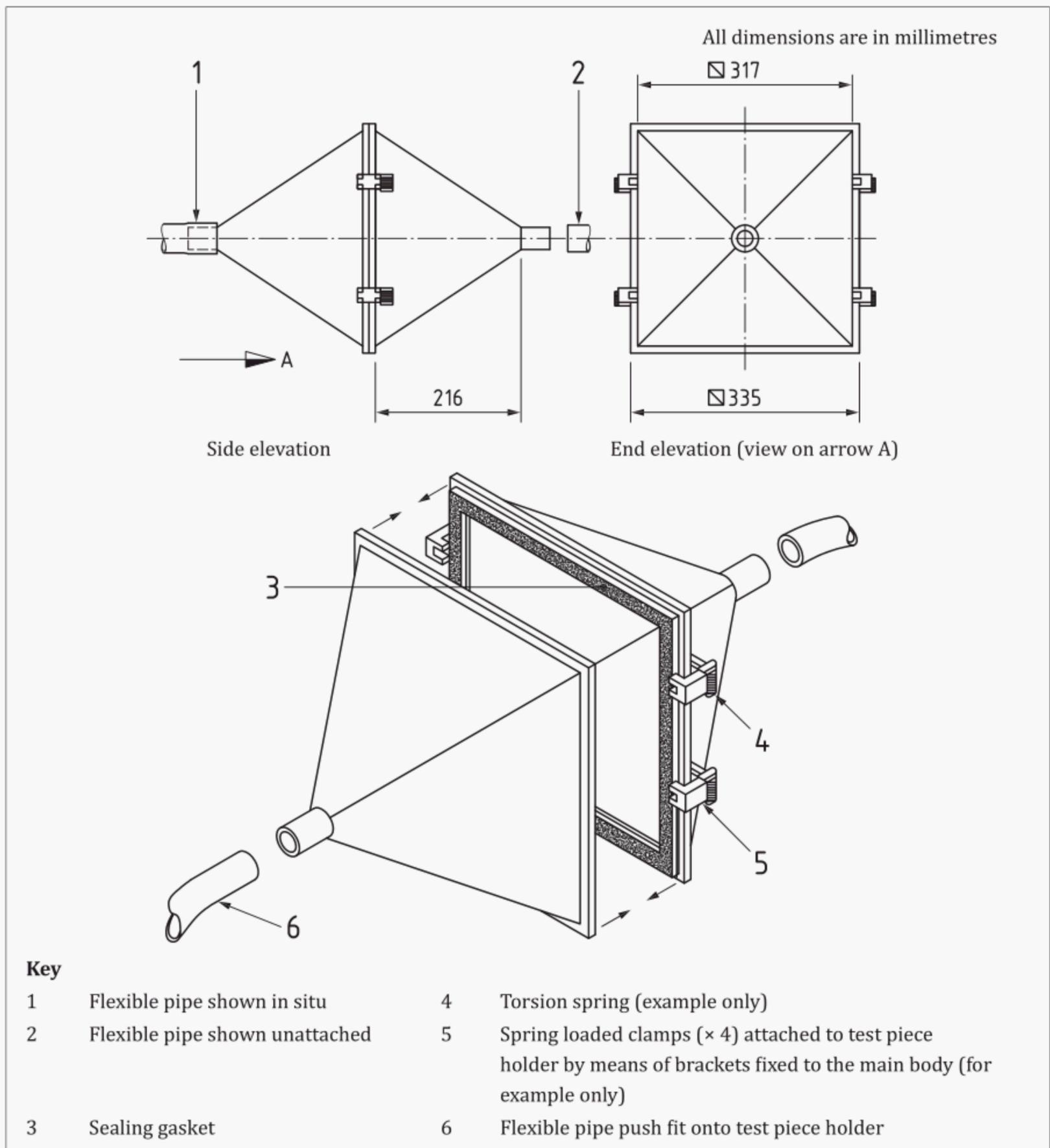


Figure 2 — Test piece holder for methylene blue particulate penetration test

5 Apparatus, components and layout

NOTE See [Annex A](#) and [Figure 1](#).

- 5.1** *Test cloud generator*, comprising the atomizer (A), needle valve (V_1), pressure gauge (D), compressed air flowmeter (M_1) and evaporation tube (E).
- 5.2** *Control cock* (C).
- 5.3** *Test circuit*, comprising test piece holder (T), test paper holder (F), flowmeter (M_2) and control valve (V_2).
- 5.4** *Bypass circuit*, comprising the filter (G), flowmeter (M_3) and control valve (V_3).
- 5.5** *Filter paper* (3).

5.6 Rotary suction pump.

5.7 Air drier.

6 Procedure

6.1 Preliminary

6.1.1 Fill the atomizer with a 1% methylene blue solution up to a level 6 mm below that of the spray orifice: approximately 500 ml of solution are required.

6.1.2 After a maximum of 8 h operation, discard the methylene blue solution and replace with a fresh 1% solution of methylene blue.

NOTE The methylene blue solution in the atomizer with the standard nozzle is consumed at a rate of approximately 10 ml per hour. This loss is due in part to the atomization of the solution and in part to the evaporation of water from the main bulk of the liquid. The concentration of the solution in the reservoir therefore increases steadily during the operation of the apparatus. The volume of the reservoir is chosen so that the change in concentration, and loss of volume, of the solution during a period of 8 h operation or less, will not cause an appreciable change in the concentration of the test cloud.

6.2 Start-up instructions

6.2.1 Start up the apparatus as follows.

- a) Turn the control cock (C) to OFF.
- b) Switch on the suction pump.
- c) Close and clamp the unloaded test piece holder (T).
- d) Clamp the unloaded test paper holder (F) firmly closed.
- e) Turn the control cock (C) to TEST.
- f) Adjust the air valve (V_2) to give a flow of 30 dm³/min through the bypass circuit.
- g) Turn the control cock (C) to OFF.
- h) Adjust control valve (V_3) to give a flow of 30 dm³/min through the test circuit.
- i) Turn on the compressed air to the atomizer and adjust the needle valve (V_1) until the pressure gauge (D) registers 205 kPa. The ball in the compressed air flowmeter (M_1) should now rise to the calibration mark. If the air flow is insufficient, turn off the compressed air and clear the atomizer jets.

NOTE 1 Steps e) to h) establish the nominal air valve settings to give the required flow rates in subsequent operations. Minor adjustments only from these settings can be made.

NOTE 2 For details of maintenance, see [Clause 8](#).

6.2.2 Maintain the air pressure at a constant of 205 kPa. The air pressure is not to be increased to bring the air flow up to the correct value.

6.3 Preparation of standard stains

Prepare the standard stains as follows.

- a) Close and clamp the unloaded test piece holder.
- b) Clamp a short piece of filter paper in the test paper holder.
- c) Turn the control cock (C) to TEST for 20 s. During this period check, and adjust if necessary, the air valve (V_2) in the test circuit to give a flow rate of 30 dm³/min.

- d) Turn the control cock (C) to OFF.
- e) Unclamp the test paper holder and discard the piece of filter paper.
- f) Insert and clamp in the test paper holder the end of a 300 mm length of filter paper.
- g) Turn the control cock (C) to TEST, hold for 1 s and then turn to OFF.
- h) Unclamp the test paper holder, move the strip 25 mm to one side and reclamp.
- i) Repeat steps g) and h) but for 2 s duration.
- j) Repeat the sequence, increasing the duration of the run by 1 s on each up to 10 s.
- k) Remove the filter strip and expose it to a jet of steam until the intensity of the stains is fully developed.

NOTE This filter strip, with 10 stains of increasing intensity, is the standard test strip against which the test stains are compared. The 1 second stain is equivalent to a 2.5% penetration when the test is run for 40 s. Successive stains represent increments of a 2.5% penetration so that the 10 second stain corresponds to a 25% penetration.

6.4 Preparation of test stains

6.4.1 Prepare the test stains as follows:

- a) cut two test pieces from the specimen to be tested, each 400 mm × 400 mm, and condition them in accordance with BS EN 20187 for not less than 24 h. Carry out the remainder of the test within 10 mins of removal of the test pieces from the conditioning atmosphere;
- b) turn the control cock (C) to OFF;
- c) clamp a test piece into its holder such that the wire side is challenged by the test cloud;
- d) clamp a short length of filter paper into the test paper holder;
- e) turn the control cock (C) to TEST and after 10 s to OFF. During this period, check, and, if necessary, adjust the flow rate of the test circuit to 30 dm³/minute;
- f) discard the piece of filter paper and replace with a fresh piece;
- g) turn the control cock (C) to TEST and after 40 s turn to OFF;
- h) remove the test piece and the piece of filter paper. Develop the stain on the filter paper using a jet of steam; and
- i) repeat steps c) to h) using the other test piece and testing the other side of the specimen.

6.4.2 Under the identical lighting conditions, compare the test stains with the standard stains and visually match them.

7 Expression of results

Report the test results for each side of the test sample in terms of percentage penetration.

8 Maintenance of apparatus

8.1 The jets of the atomizer shall be cleaned periodically.

NOTE Blocking of the jets is shown by a decrease in the flow through the compressed air flowmeter.

8.2 The control cock shall be removed when necessary and the ports and bearing surfaces cleaned. The plug shall then be lubricated with a soft grease and replaced.

- 8.3** Accumulations of blue shall be removed periodically from the rubber connecting pipes, particularly those from the evaporation tube to the control cock, the control cock to the test piece holder and the test piece holder to the filter paper clamp.
- 8.4** The tubes shall be removed and washed out with deionized water. The bore shall be dried before the tubing is replaced. If a stain is obtained on the test paper when air only is passed through a test piece holder, i.e. when the control cock is turned to the AIR position and not the TEST position, the connections from the test piece holder to the test paper holder shall be cleaned.
- 8.5** In order to minimize the collection of blue in this pipe, the control cock shall not be turned to TEST when there is no test piece in the test piece holder.
- 8.6** The standard stains shall be renewed frequently whenever the paper becomes soiled or when fading is apparent. Fading can be minimized by keeping the strip in the dark when not in use.

Annex A (normative)

Specification of components of the apparatus

COMMENTARY ON Annex A

Alternative threads of equivalent size to those described in this annex may be used.

A.1 Assembly of test apparatus

- A.1.1** Mount the apparatus on a table or bench approximately 1 200 mm long by 600 mm wide. A vertical panel approximately 300 mm high, extending the full length of the table and 40 mm from the front edge, shall be provided.
- A.1.2** The control cock, test piece holder and test paper holder are mounted on the table, and the test circuit flowmeter, by-pass circuit flowmeter, air valves, pressure gauge, needle valve and compressed air flowmeter are mounted on the panel (see [Figure A.1](#) and [Figure A.2](#) for examples of the assembly of apparatus). The atomizer and evaporation tube shall be placed behind the panel.
- A.1.3** The angle of inclination at which the flowmeters are mounted shall be determined during the preliminary calibration of these components.

NOTE The air compressor and rotary suction pump may be placed in any convenient position near the main portion of the apparatus.

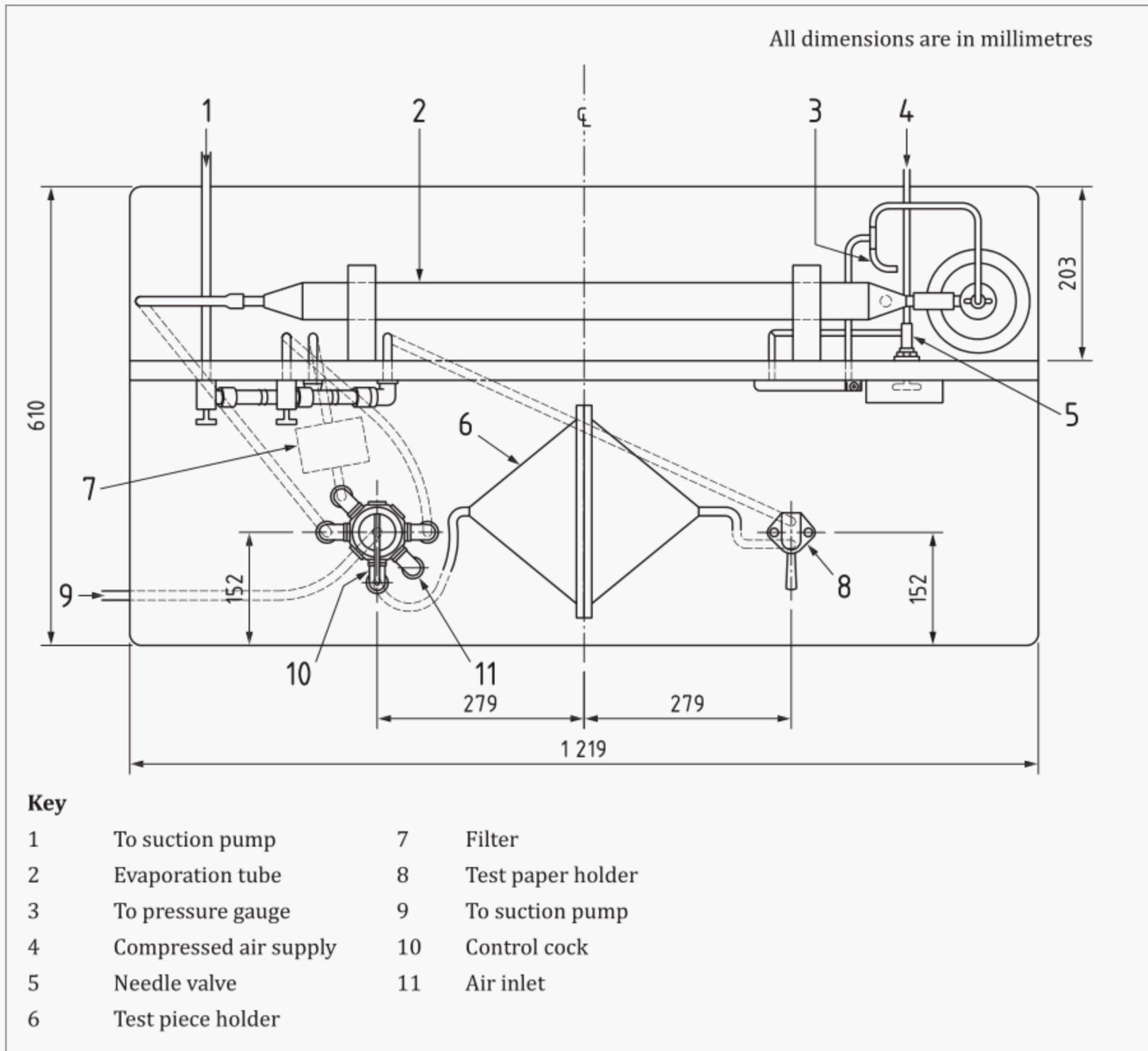
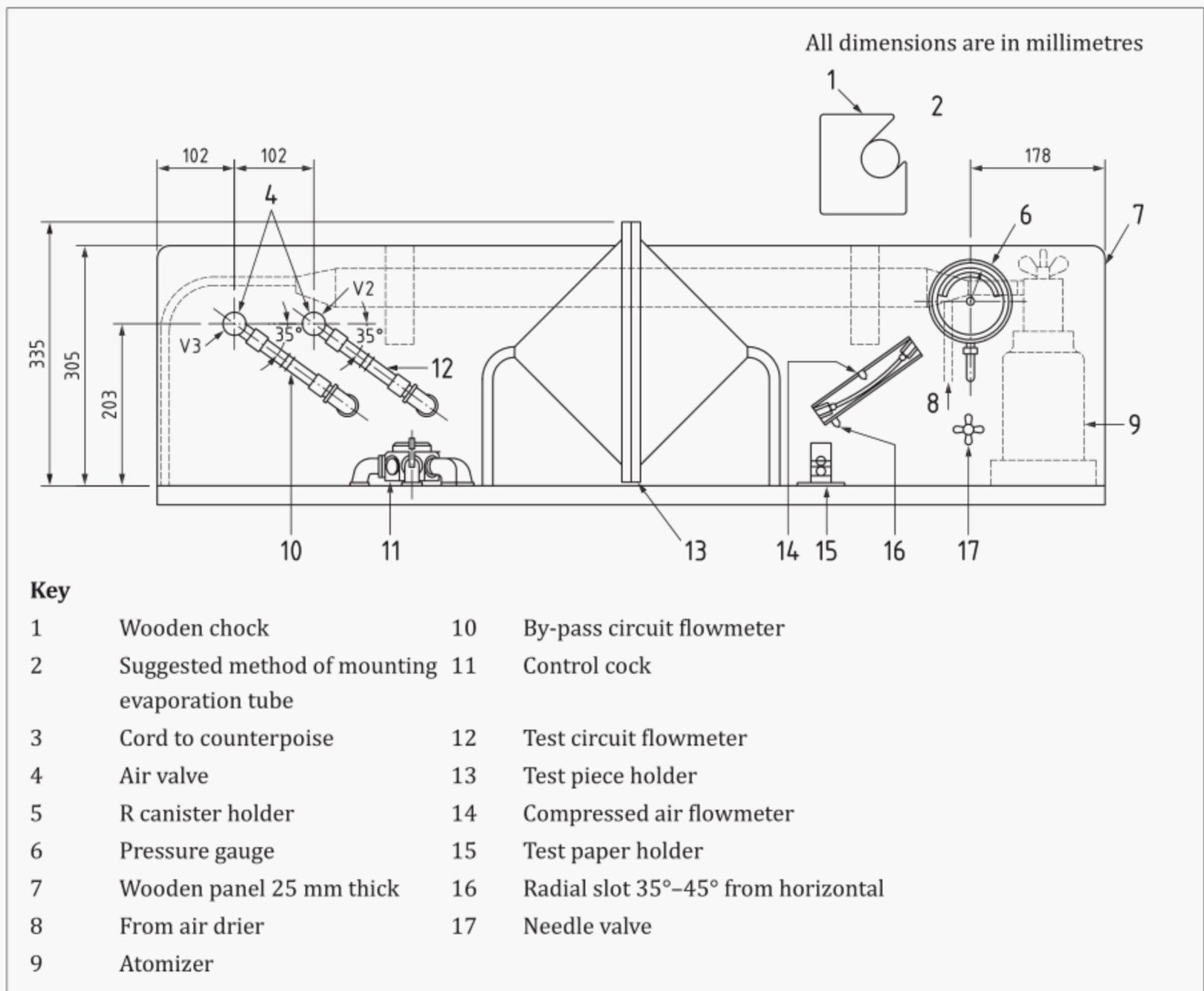
Figure A.1 — *Illustration of assembly of apparatus (plan view)*

Figure A.2 — *Illustration of assembly of apparatus (side view)*

A.2 Connections

- A.2.1** Except as stated in [A.2.2](#), connections as shown in [Figure A.1](#) and [Figure A.2](#) shall be made with rubber hose with braided or woven reinforcement of nominal diameter 16 mm.
- A.2.2** The connection between the test piece holder outlet and the movable section of the test paper holder shall be made with soft rubber tubing with nominal 16 mm bore and 3 mm wall.
- A.2.3** The outlet of the atomizer and the cloud inlet to the evaporation tube shall be placed co-axially and in contact.
- A.2.4** All connections shall be made with the minimum necessary length of tubing.
- A.2.5** At no point shall the connecting tubing be bent sharply or kinked so as to cause any constriction of the bore.

A.3 Calibration of flowmeters

A.3.1 General

After assembly of the apparatus, the flowmeters shall be calibrated under working conditions in accordance with [A.3.2](#), [A.3.3](#) or [A.3.4](#), as applicable.

A.3.2 Test circuit flowmeter

- A.3.2.1 Place a piece of card in the filter paper clamp on the test piece holder and close the clamp firmly in order to prevent the entry of air into the inlet duct at this point.
- A.3.2.2 Disconnect the atomizer from the evaporation tube and block the cloud inlet of the evaporation tube.
- A.3.2.3 Remove the air drier and connect a standard flowmeter to the evaporation tube air inlet.
- A.3.2.4 Place a strip of filter paper in position in the test paper holder.
- A.3.2.5 After setting the suction pump in operation, turn the control cock to the test position and adjust the air valve in the test circuit until the standard meter indicates a flow of 30 dm³/min.
- A.3.2.6 Mark the position of the ball in the sight tube of the test circuit flowmeter.

A.3.3 By-pass circuit flowmeter

- A.3.3.1 With connections as in [A.3.2](#), turn the control cock to air. Adjust the valve in the by-pass circuit to give a flow of 30 dm³/min as shown by the standard flowmeter.
- A.3.3.2 Mark the position of the ball in the sight tube of the by-pass circuit flowmeter.

A.3.4 Compressed air flowmeter

- A.3.4.1 Assemble the atomizer with no liquid in the glass reservoir.
- A.3.4.2 Connect the outlet tube of the atomizer to the standard flowmeter.
- A.3.4.3 Turn on the compressed air and adjust the needle valve until a pressure of 205 kPa is shown on the pressure gauge.

NOTE If the jets of the atomizer are not blocked or otherwise damaged, the flow should now be between 8 and 8.5 dm³/min.

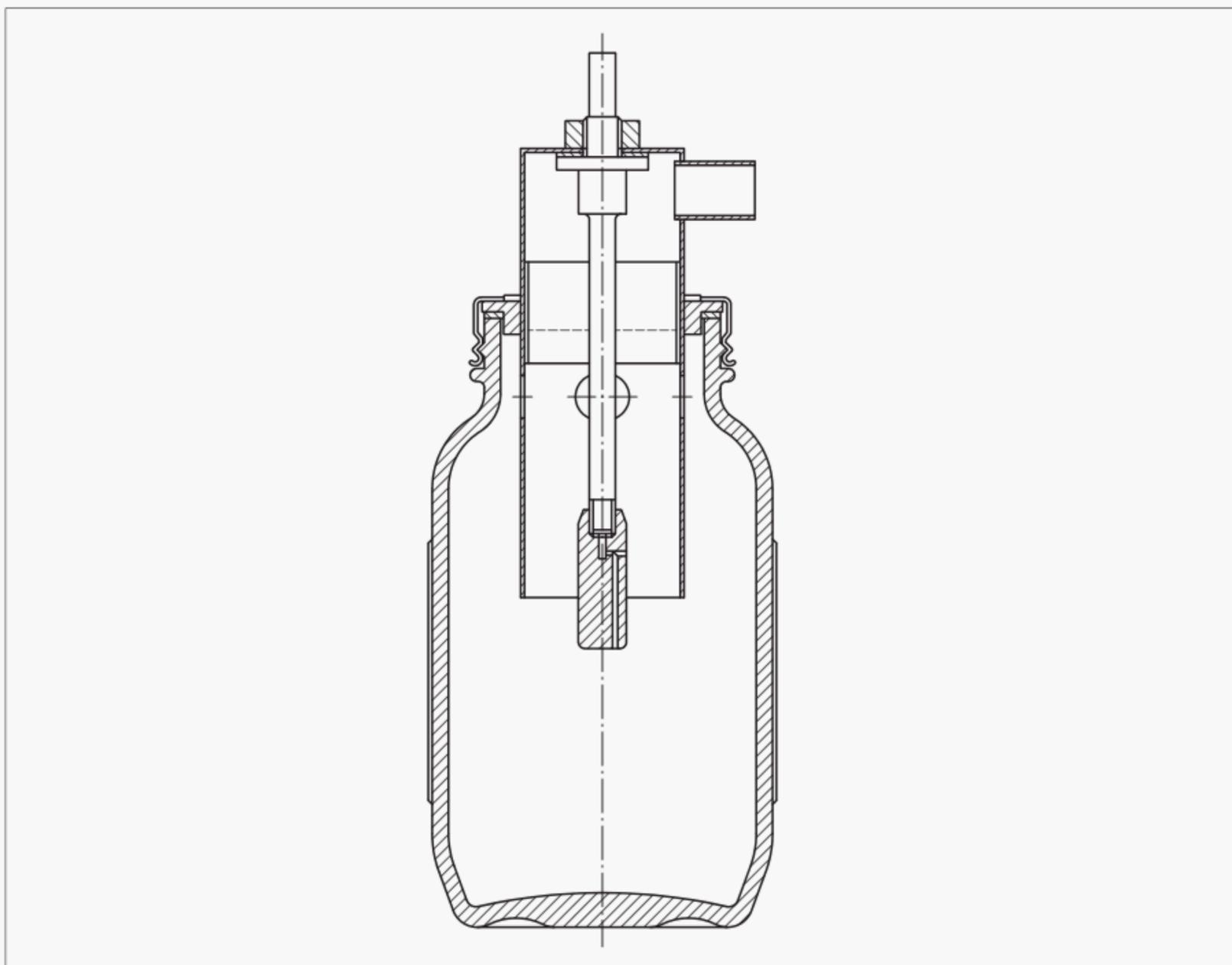
Examine the standard flowmeter and verify that the flow is within the above limits.

- A.3.4.4 Mark the position of the ball in the sight tube of the compressed air flowmeter.
- A.3.4.5 If the standard flowmeter does not show the air flow to be between 8 and 8.5 dm³/min, examine the atomizer for blocked jets, leaking connections or other faults. Remedy any fault identified.
- A.3.4.6 During subsequent operation of the apparatus, the flow of compressed air shall remain constant at the value for which the meter was set. Any deviation from this value indicates faults as described in [A.3.4.5](#). Any faults identified shall be remedied.

A.4 Atomizer

The atomizer shall conform to [Figure A.3](#) and shall be assembled in the manner indicated in the drawing from component parts detailed in [Table A.1](#).

NOTE See also [Figure A.4](#) to [Figure A.6](#).

Figure A.3 — *Atomizer assembly***Table A.1** — *Components of atomizer*

Component	Quantity
Atomizer head ^{A)}	1
Sleeve	1
Nozzle (3 jet)	1
Compressed air connection	1
Wing nut	1
Glass reservoir	1
Locking ring	1
Rubber washer	1

^{A)} See also [Figure A.4](#).

Figure A.4 — Atomizer head

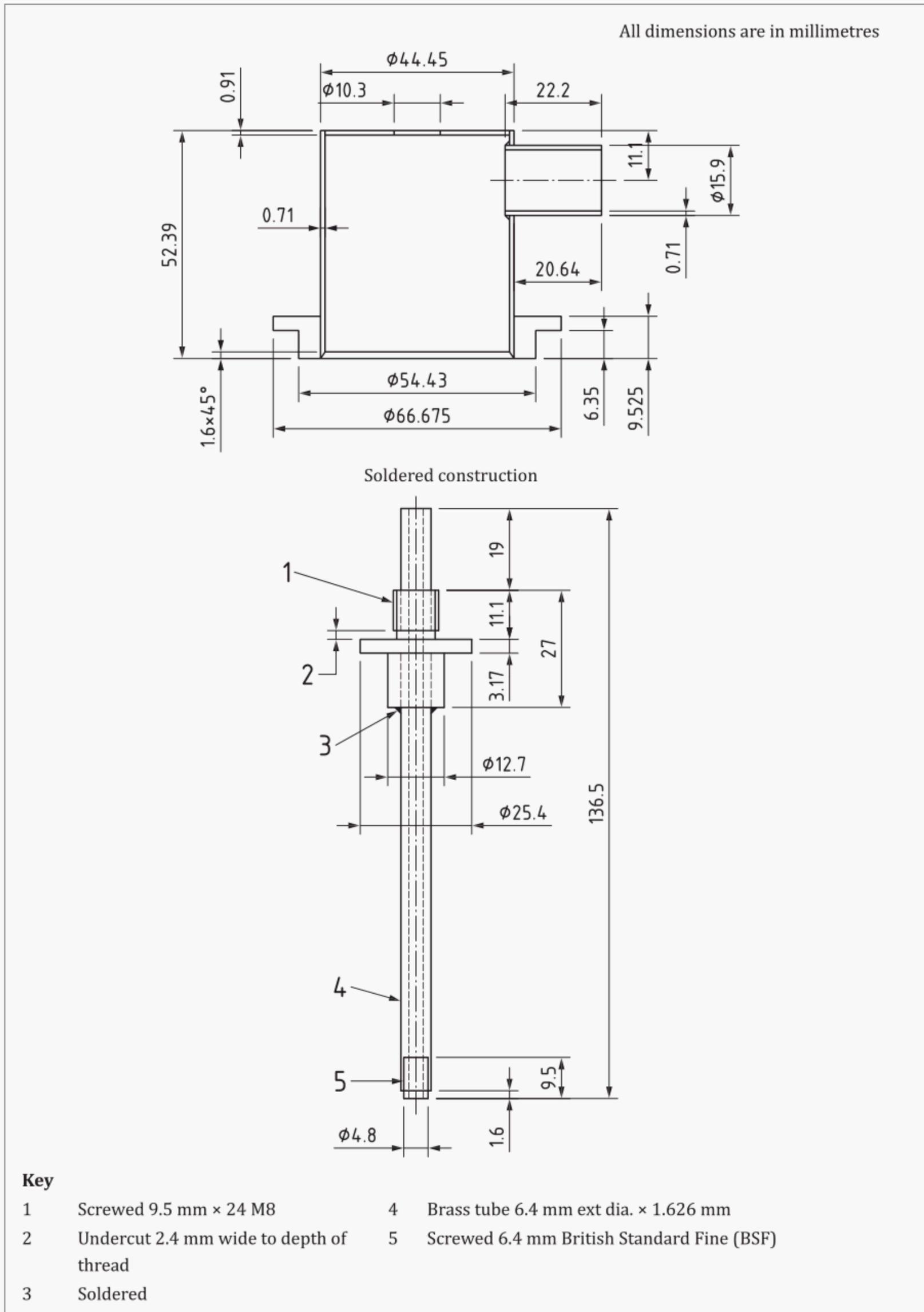


Figure A.5 — Nozzle. Material: brass

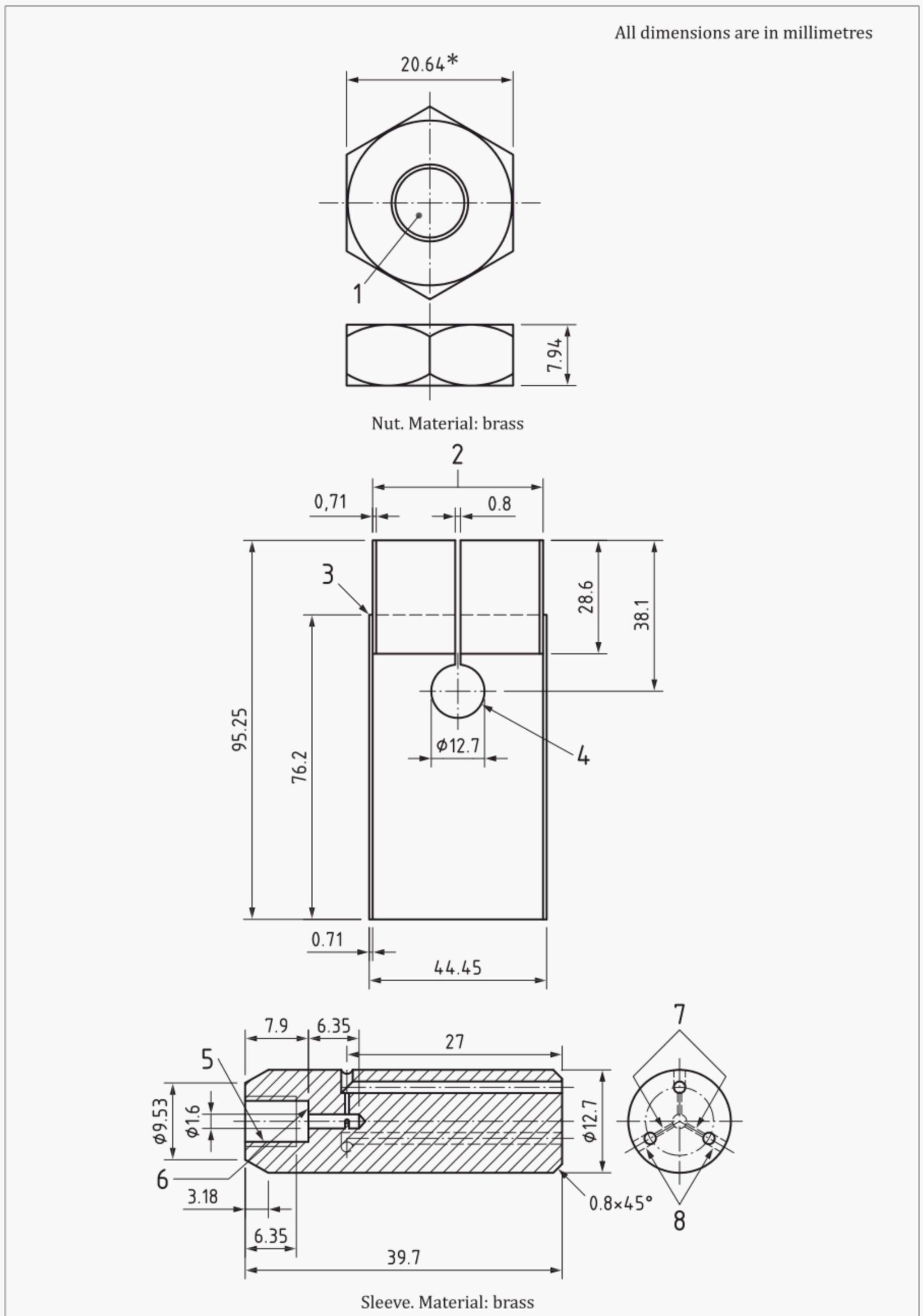
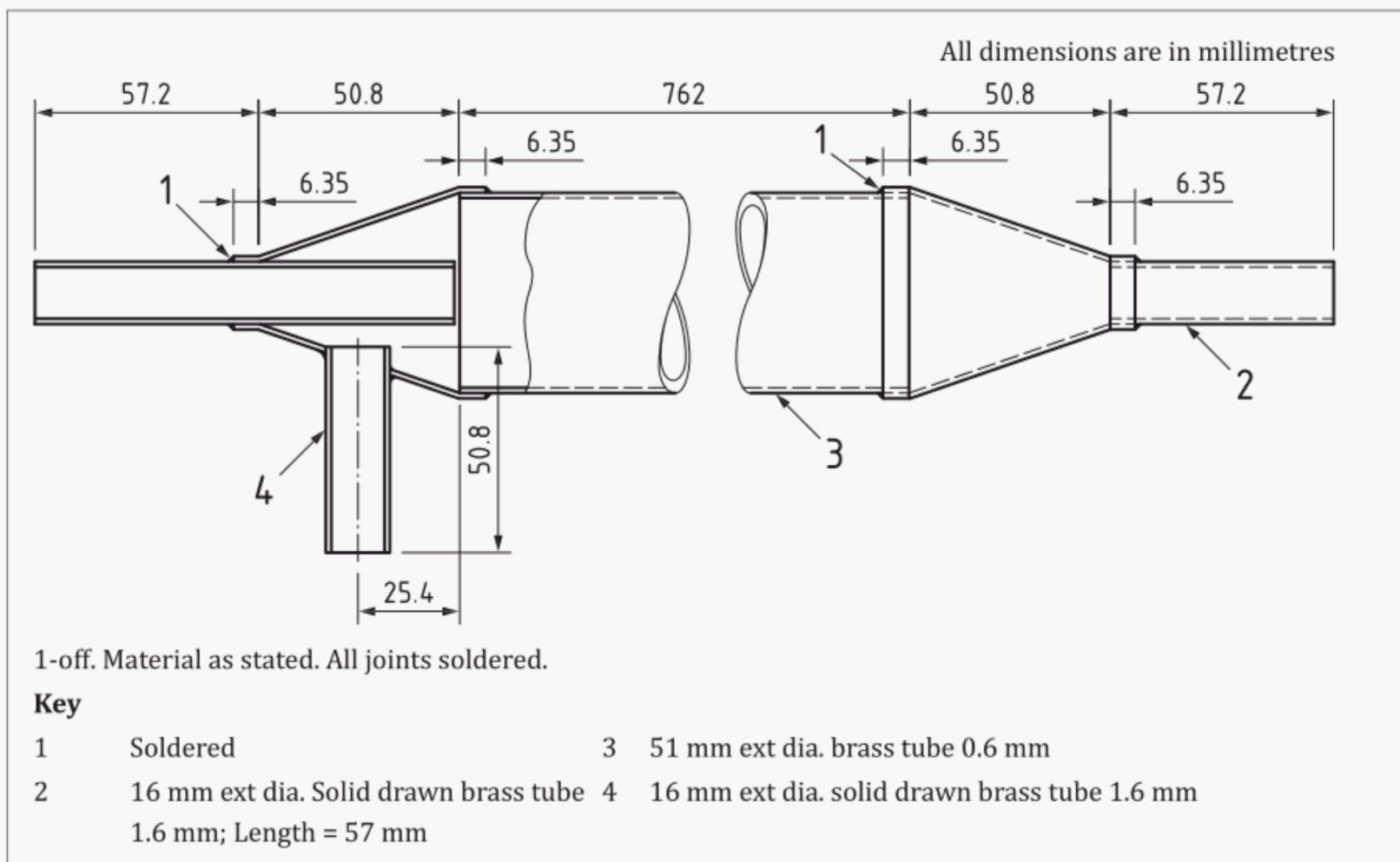


Figure A.5 (continued)

Key	
1	Screwed 9.5 mm × 24 M8
2	Diameter to be a push fit in item 2
3	Sweated
4	Four equal holes and slots equally spaced circumferentially
5	Tapped 6.4 mm BSF
6	Seating to be flat
7	Three holes 0.3 mm dia. (No. 80 drill)
8	Three holes 1.6 mm dia. equally spaced on 8 mm pitch circle dia.

Figure A.6 — Evaporation tube



A.5 Control cock

A.5.1 The control cock shall conform to [Figure A.7](#) and be assembled in the manner indicated in the drawing from the component parts detailed in [Table A.2](#).

Table A.2 — Components of the control cock

Component	Quantity
Body	1
Plug	1
Nipple	5
Elbow	5
Screwed plug	1
Tube	6
Backnut	1
Operating handle	1

A.5.2 The body shall be made of gunmetal or brass and shall be machined to the form and dimensions indicated in the drawing. The metal shall be sound and free from blow holes or other defects.

NOTE See [Figure A.7](#) and [Figure A.8](#).

A.5.3 The plug shall be made of gunmetal or brass and shall be machined to the form and dimensions indicated in the drawing. The metal shall be sound and free from blow holes or other defects. The taper shall be machined to ensure a gas-tight fit between the ports on assembly.

A.5.4 All screw threads shall conform to the corresponding British Standard and all screwed connections shall be made airtight on assembly.

A.5.5 The handle shall conform to [Figure A.9](#).

Figure A.7 — Control cock

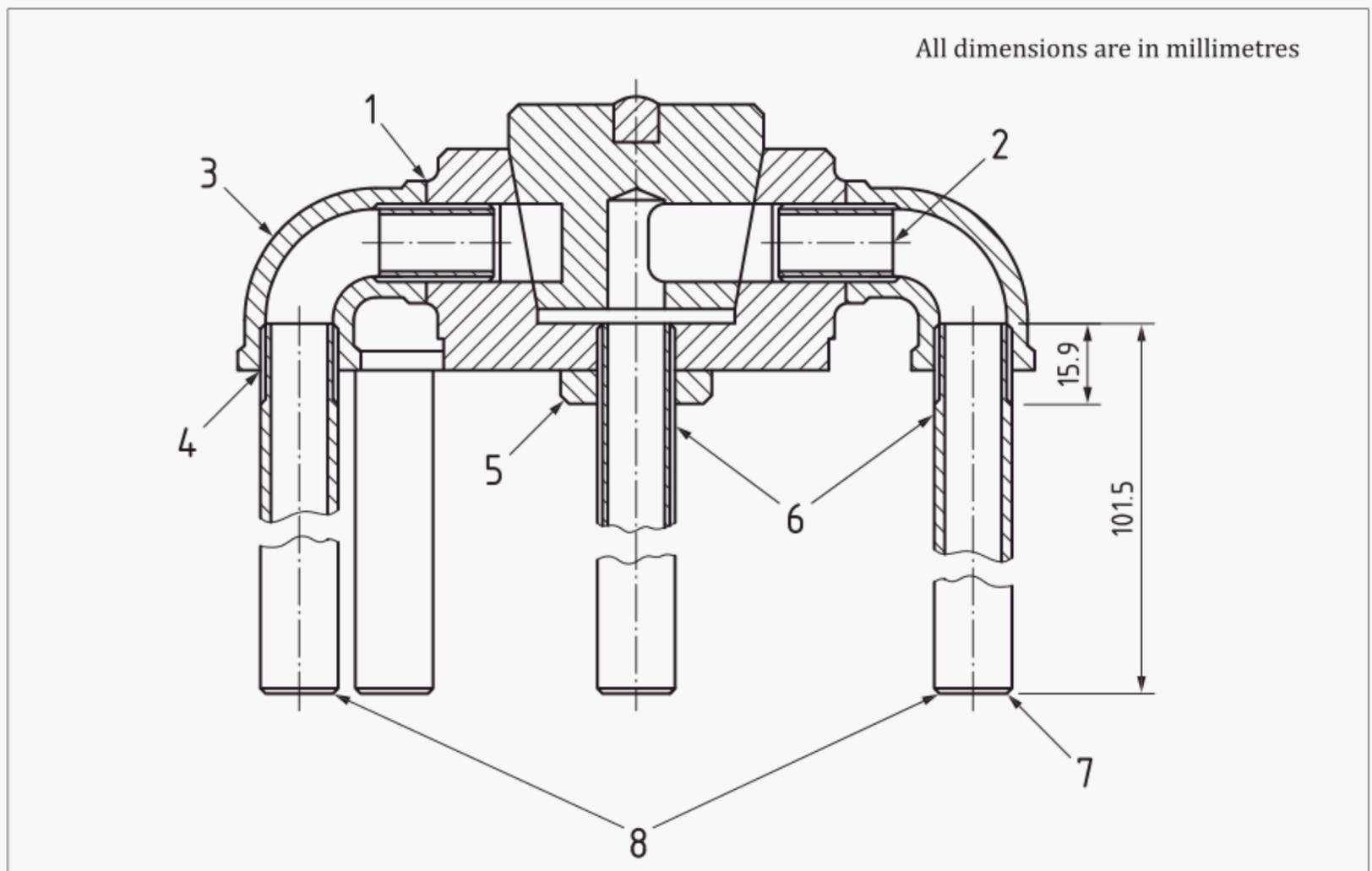


Figure A.7 (continued)

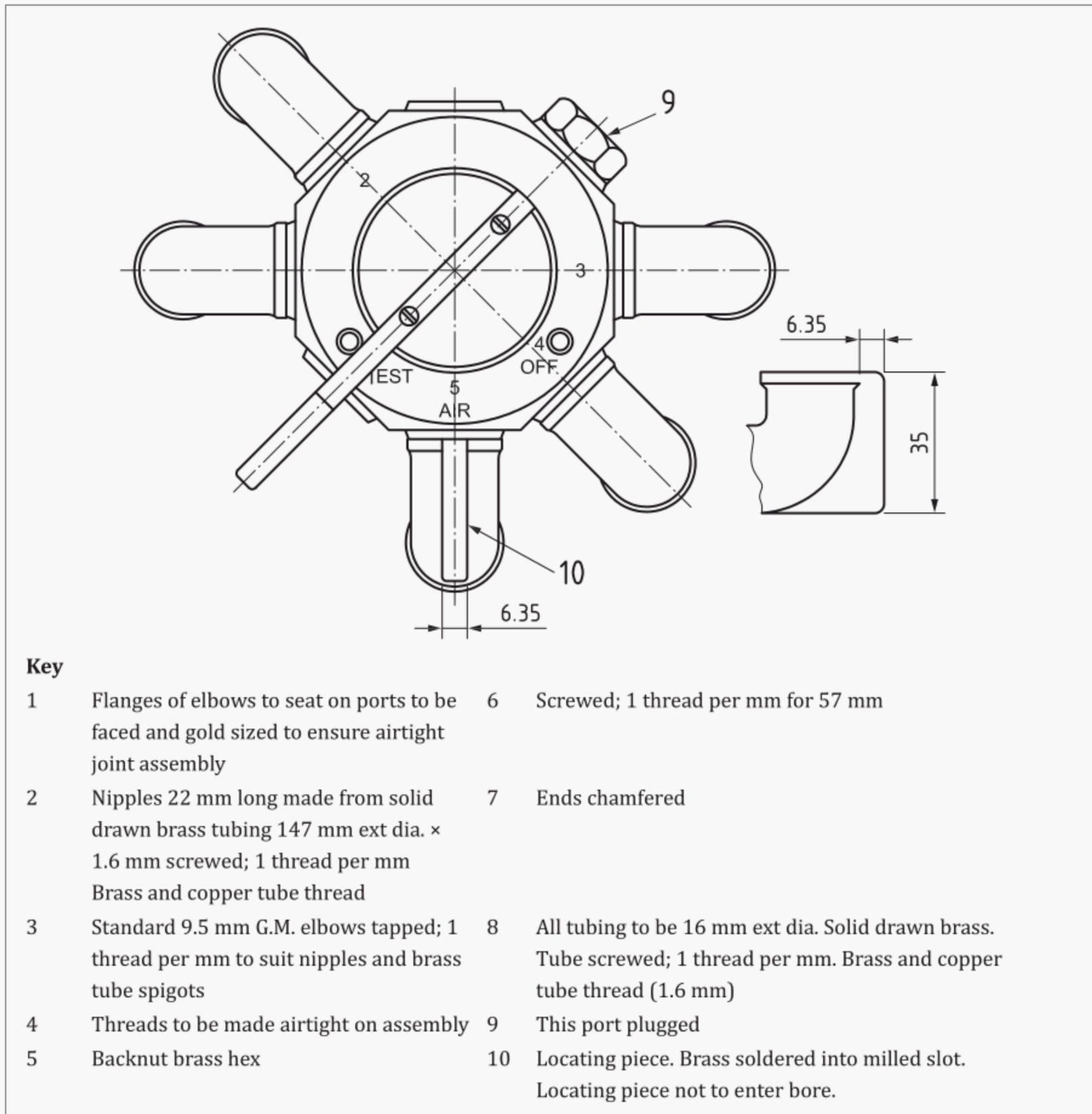


Figure A.8 — Control cock body

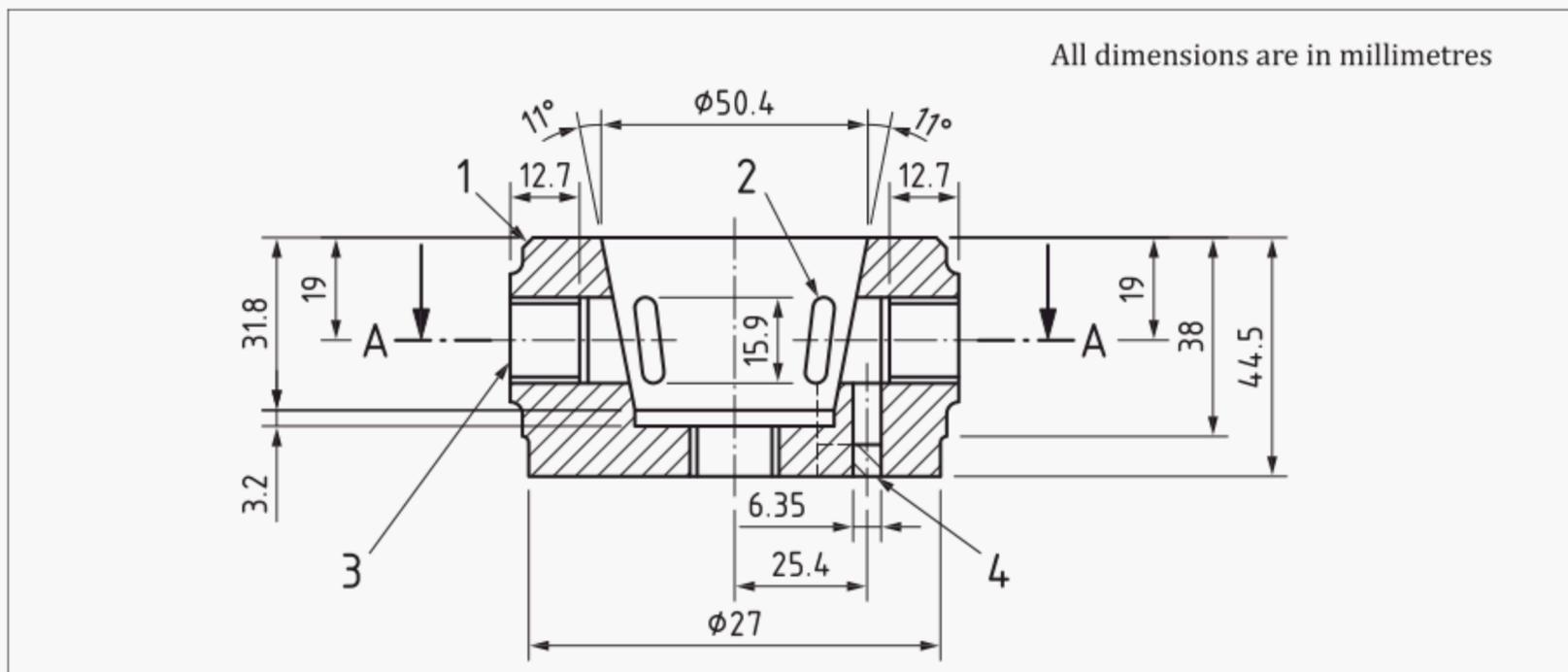


Figure A.8 (continued)

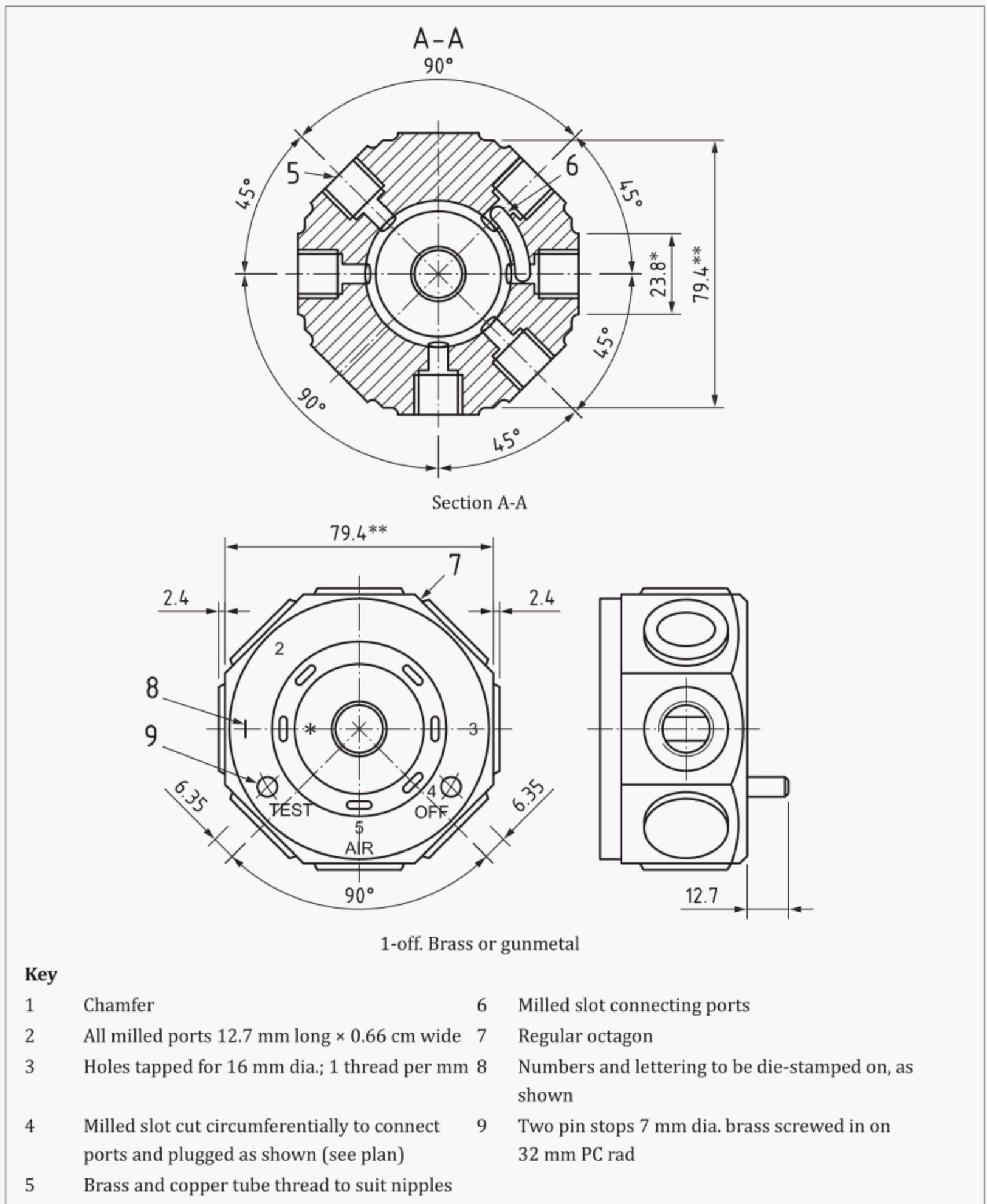
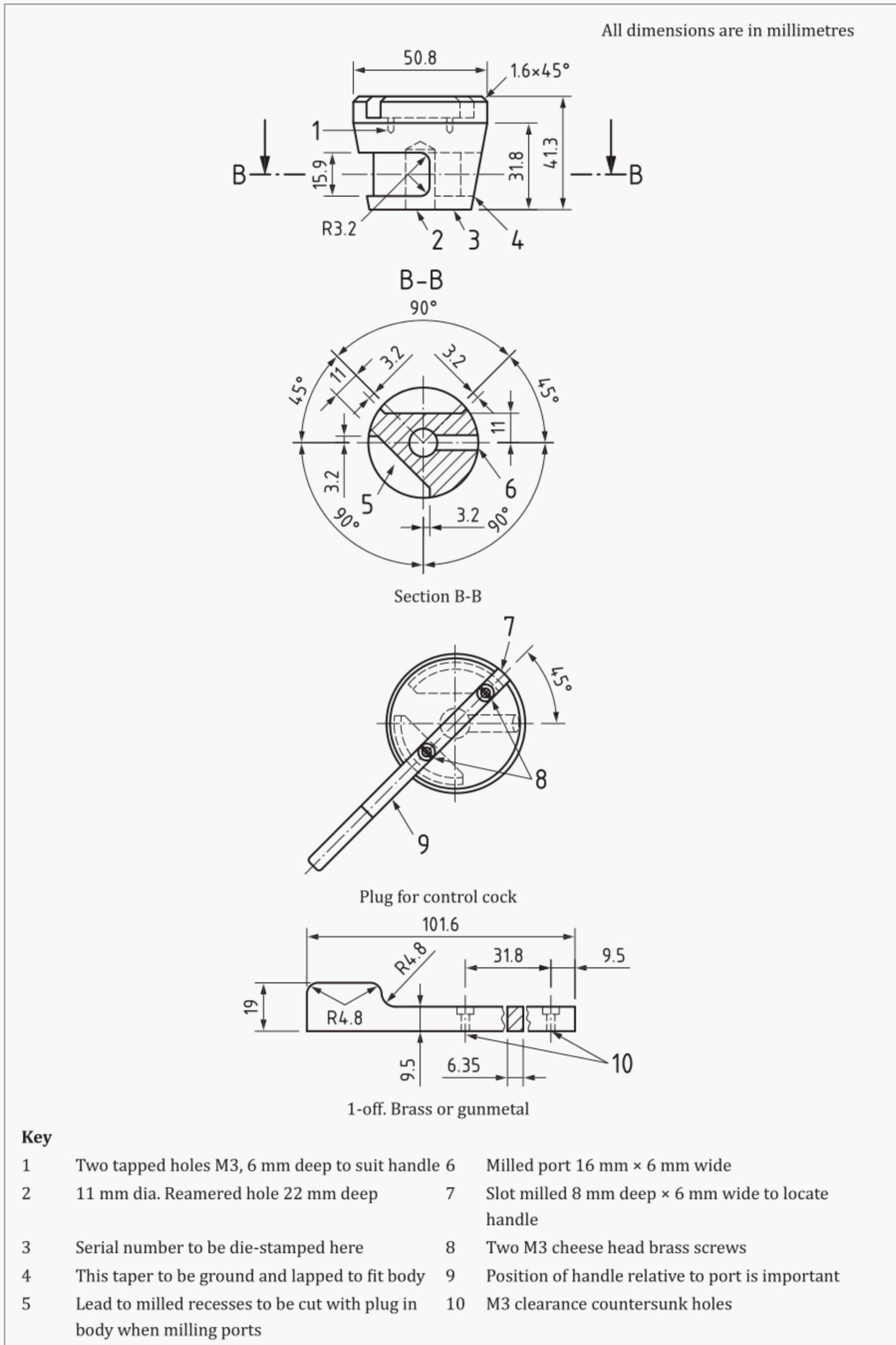


Figure A.9 — Handle



A.6 Test paper holder

- A.6.1** The test paper holder shall conform to [Figure A.10](#).
- A.6.2** The surfaces between which the paper is clamped shall be machined flat and square with the tread to ensure a substantially airtight seating when the clamp is closed.
- A.6.3** The bore of the clamp shall be reamed out to a diameter as indicated in [Figure A.10](#).
- A.6.4** The base plate shall conform to [Figure A.11](#) and the handle to [Figure A.12](#).

Figure A.10 — *Assembly of test paper holder*

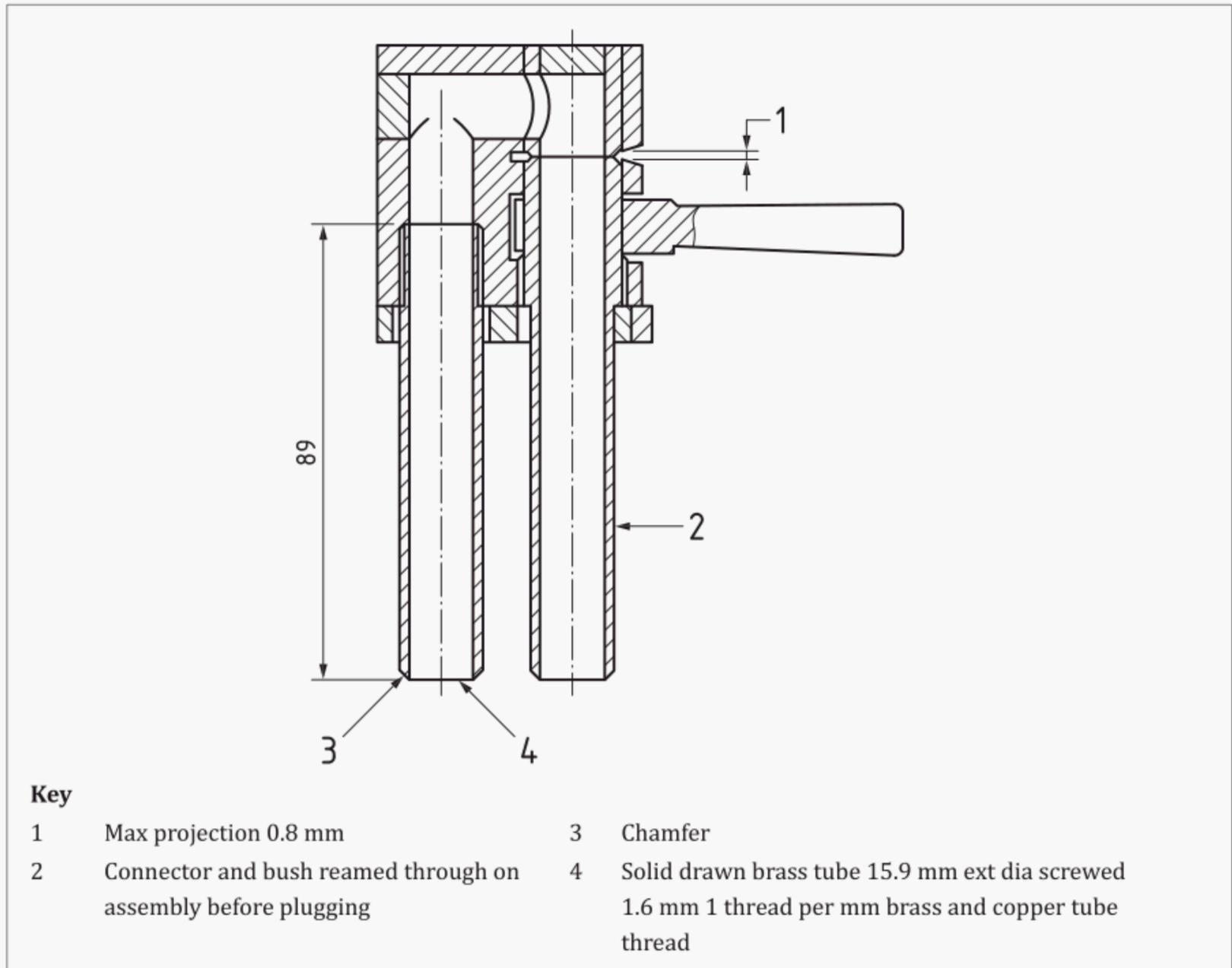


Figure A.11 — Base plate

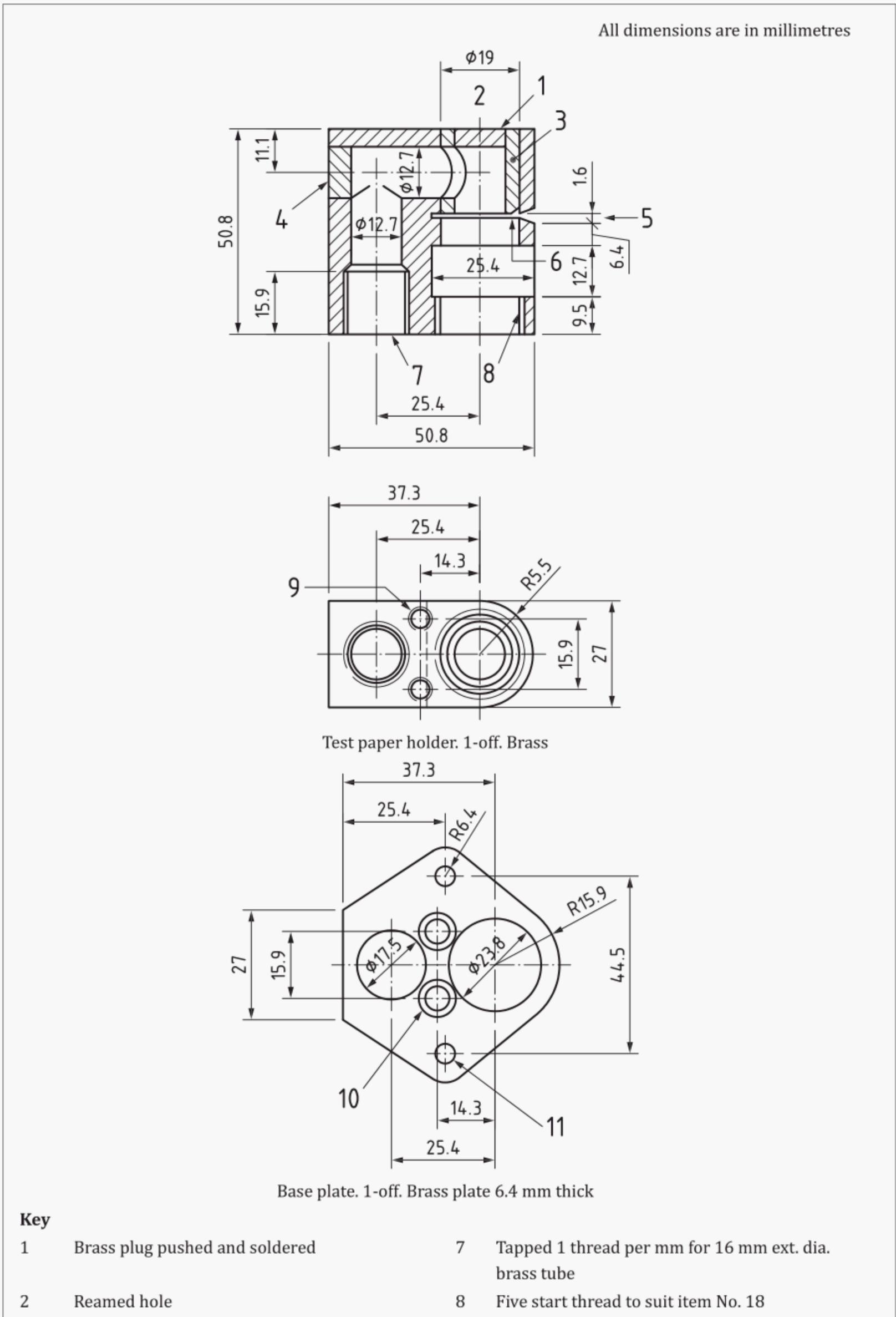
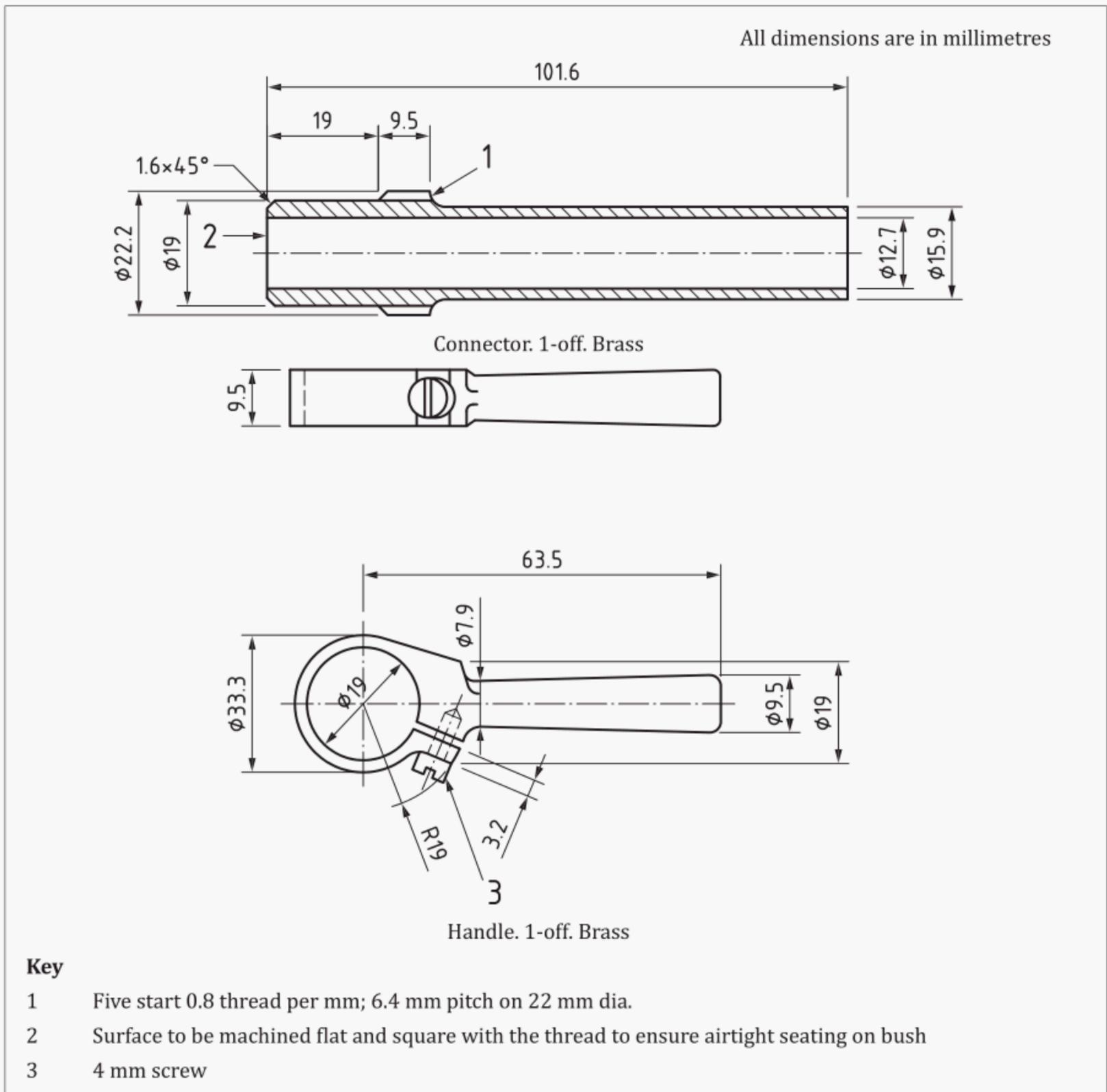


Figure A.11 (continued)

3	Brass push 21 mm long × 13 mm bore edge slightly protruding in paper slot and chamfered 1.6 mm	9	Two holes tapped M5
4	Brass plug	10	Two countersunk holes for M5
5	Filter paper slot 25 mm deep entry chamfered	11	Two holes for M5
6	Surface to be machined flat to ensure airtight seating on connector		

Figure A.12 — Handle



A.7 Flowmeter and air valve

A.7.1 The flowmeters shall be of the variable area type and shall be fitted with air regulating valves.

A.7.2 All screw threads shall be a good fit and rubber connections shall be made airtight.

A.7.3 The flowmeters shall be calibrated for a flow of 30 dm³/min of free air at their working pressures. A final calibration shall be carried out after the complete assembly of the apparatus.

A.8 Compressed air flowmeter

A.8.1 One compressed air flowmeter, of the variable area type, to measure flow of 8 dm³/min of free air at a pressure of 205 kPa shall be used.

A.8.2 The ball of the flowmeter shall run freely in the sight tube.

A.9 Pressure gauge

The pressure gauge shall be of the bourdon type, reading up to 275 kPa, with a 100 mm dial.

A.10 Needle valve

The needle valve shall be suitable for controlling an air flow of 8 dm³/min of free air at a pressure of 205 kPa. It shall be adapted for panel mounting.

A.11 Evaporation tube

The evaporation tube shall conform to [Figure A.6](#).

A.12 Filter

One filter holder which conforms to [Figure A.13](#), [Figure A.14](#) and [Figure A.15](#) shall be used.

NOTE A 5.0 g pad of superfine glass fibres is a suitable filter medium.

Figure A.13 — Assembly

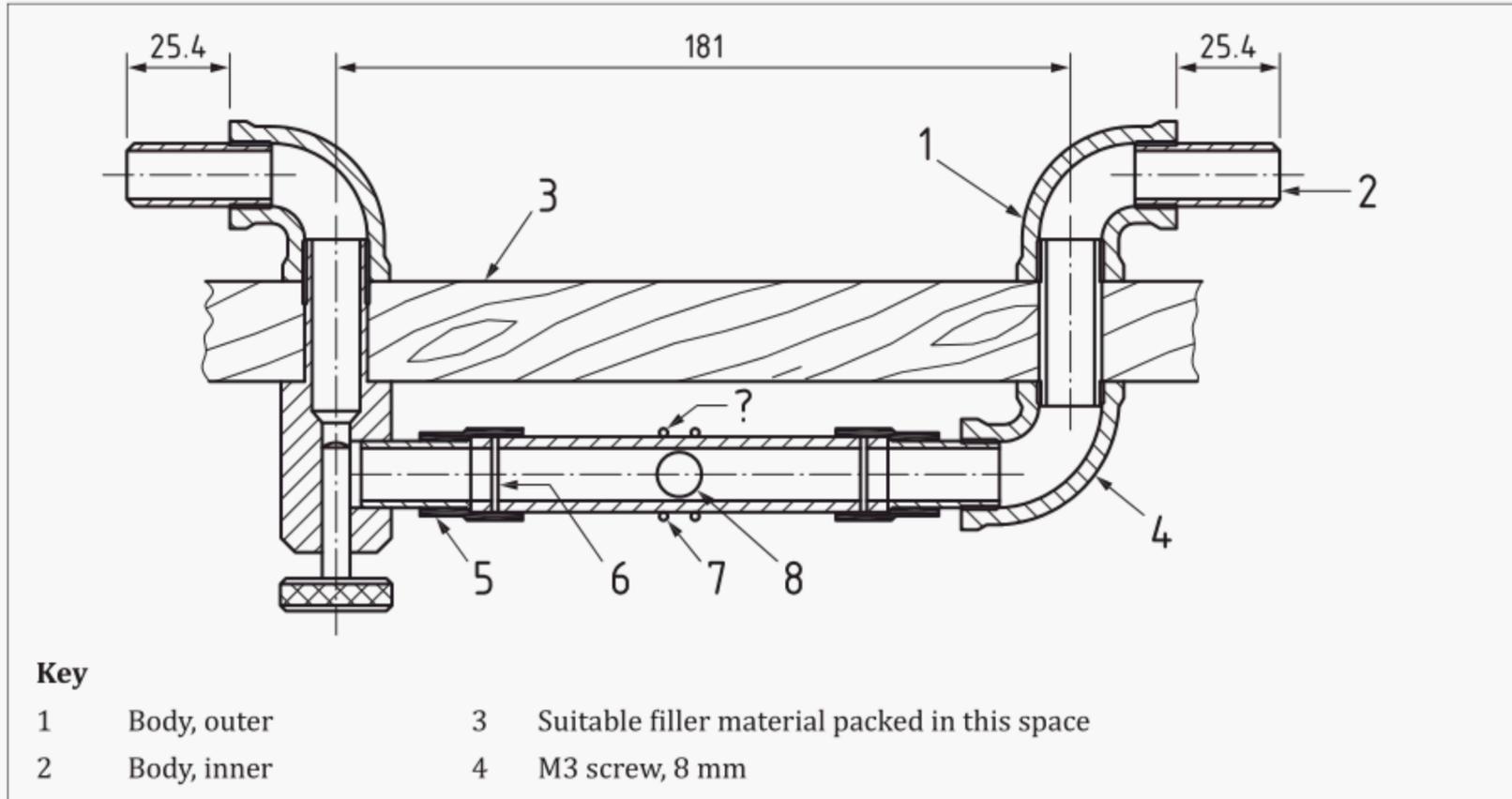


Figure A.14 — Cap

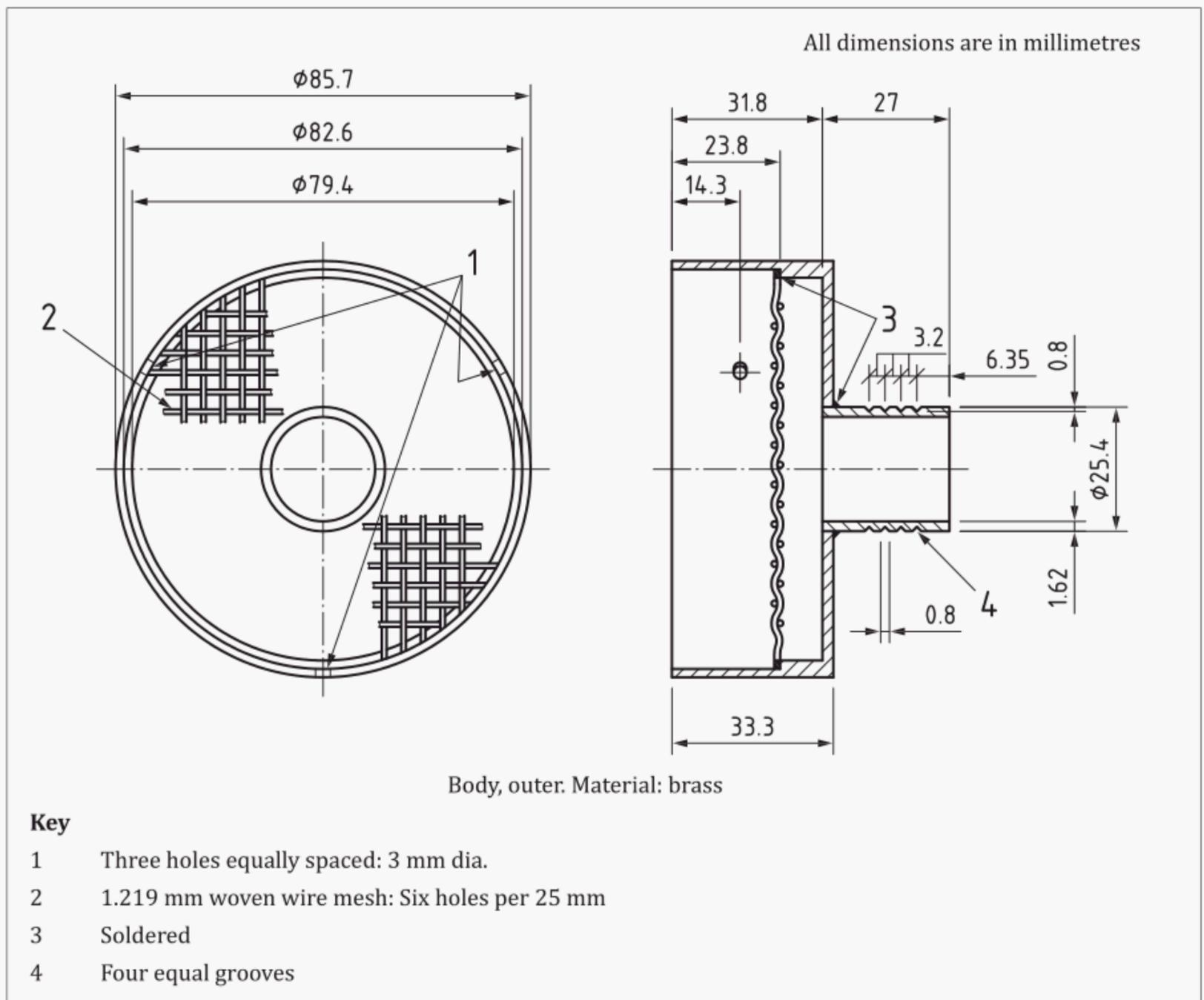
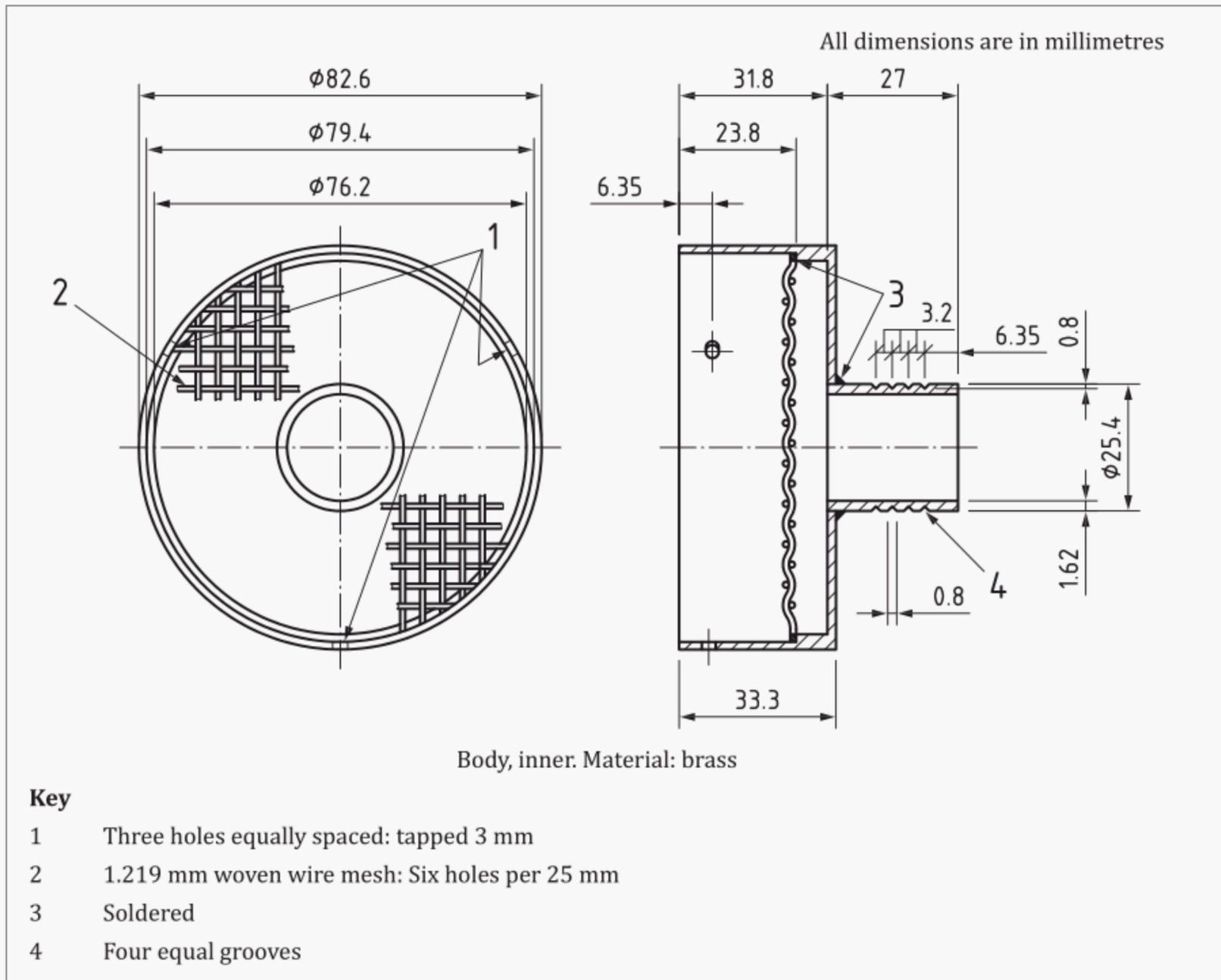


Figure A.15 — Holder



A.13 Test piece holder

The test piece holder shall conform to [Figure 2](#).

A.14 Air drier

- A.14.1** The air drier shall be of sufficient capacity to dry 30 dm³ of air per minute for 8 h. The resistance of the drier at an air flow of 30 dm³/min shall not exceed 250 kPa. The relative humidity of the dried air shall not exceed 20%.
- A.14.2** A calcium chloride drying tower can be used. The calcium chloride can be a technical fused porous lump and shall be free from dust.

A.15 Timer

- A.15.1** The timer shall read in minutes and seconds.
- A.15.2** The timer shall be fitted with a start and stop mechanism and with a device to reset the timer to zero.

A.16 Water heater

A water heater fitted with a steam outlet to provide a jet of steam shall be provided for the development of test stains.

A.17 Accessory apparatus

A.17.1 A source of compressed air capable of delivering 10 dm³ of free air per minute at a constant pressure of 245 kPa shall be provided. The air shall be delivered clean and free from water or oil. The pressure of the supply shall remain constant to within 7 kPa.

NOTE The pressure can be stabilized by means of a pressure-reducing valve.

A.17.2 A rotary vacuum pump, or other device, capable of giving a constant reduced pressure of 35 kPa below atmospheric pressure for flows up to 1.2 dm³ per second shall be used.

A.18 Filter paper

A.18.1 The paper shall be of smooth texture and with good filtering properties.

A.18.2 The resistance of the paper to air flow shall be such that a flow of not less than 30 dm³/min is obtained through a 12.5 mm diameter circle of the paper under an air pressure of 35 kPa. The paper shall be in strips 22 mm wide.

NOTE An esparto paper made from pure bleached esparto fibre with the following characteristics is suitable.

a) Substance 85 +/- 10 g/m².

b) Thickness 10.5 +/- 1.3 mm.

c) Resistance 440 +/- 100 kPa at a flow rate of 0.25 m/s.

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²⁾ Withdrawn.

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